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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/643,196	08/18/2003	Edmund J. Moran	P-156-US2	3677
27038	7590	01/12/2005	EXAMINER	
THERAVANCE, INC. 901 GATEWAY BOULEVARD SOUTH SAN FRANCISCO, CA 94080			CHANG, CELIA C	
			ART UNIT	PAPER NUMBER
			1625	

DATE MAILED: 01/12/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/643,196	MORAN ET AL.	
	Examiner	Art Unit	
	Celia Chang	1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 20 October 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 41-51 is/are pending in the application.
- 4a) Of the above claim(s) 43-51 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 41 and 42 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Applicant's election with traverse of group I, claims 41-42 in the reply filed on Oct. 20, 2004 is acknowledged. The traversal is on the ground that the searches for each group can be done without burden and the required election of single combination of compounds is improper species restriction. This is not found persuasive because it was clearly delineated in the restriction requirement that composition containing single active ingredients and compositions containing multiple active ingredients or method of using such are patentably distinct. With respect to the burden, it is noted that the multiple active ingredient composition ranged from compositions having two active compounds, to compositions containing enzyme inhibitors, immunoglobuline, macromolecules etc. without a species election, determination of a class for search can not be made, thus, extremely burdensome.

Further, it is noted that the combination of at least the sodium chromoglycate with the beta 2 adrenergic composition is prima facie obvious over Riley et al. CA 107:211584 in view of Tsuzurahara et al. Ca 91:186691. The prior art recognized that beta 2 adrenergic agonists having synergistic effect with sodium cromoglycate (CA 107) and in general a quinolinyll compound have "better" result than other beta 2 stimulants (CA 91), therefore, it would be prima facie obvious to employ the specific well known compound of the instant beta 2 adrenergic agonist with the cromoglycate motivated by the expectation that such heterocyclic structure would provide better synergism as taught conventionally. Therefore, without restriction or species election, then there could have been no patentability of all the claims.

The requirement is still deemed proper and is therefore made FINAL.

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Claims 41-42 are prosecuted. Claims 43-51 are withdrawn from consideration per 37

CFR 1.142(b).

2. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 41-42 rejected under 35 U.S.C. 101 over claims 13-14 of issued patent US 6,653,323.

Please note that claims 13-14 of the issued patent are drawn to composition of claim 4 compounds. Claim 4 contains very limited number of compounds with explicit delineation of the compounds which would constitute anticipation of the instantly claimed compound. See In re Arkley 172 USPQ 524, In re Rusching 154 USPQ 118, Ex parte A 17 USPQ2d 1716. Please note that the issued claim is very limited and explicit as to provide evidence that the skilled artisan does not have to pick and choose from many variables as to construct and use the named specific one compound, anticipation was found.

3. Claims 41-42 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 30-31 of U.S. Patent No. 6,670,376.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims are a single species encompassed by the generic claims of the issued claims for which the single species has been clearly delineated and claimed in claim 29, see col. 104, lines 49-51. The clear delineation of the active compounds in the issued claims has been protected and "claimed" by the issued claims. There is no good reason why exclusivity should be extended through the claim of a single species which has been fully embraced by the genus and claimed as a compound claim.

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The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).


Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

3. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Celia Chang whose telephone number is 571-272-0679. The examiner can normally be reached on Monday through Thursday from 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang, can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

OACS/Chang
Jan 10, 2005


Celia Chang
Primary Examiner
Art Unit 1625